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MCDERMOTT, WILL & EMERY

August 5, 2002

VIA HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, HFA-305
Room 1061
Rockville, Maryland 20857

Re: Citizens Petition Requesting FDA to Regulate Ariva™ Smokeless Compressed Tobacco Cigalett™ Bits -- Docket No. 01P-0572

Dear Sir or Madam:

On June 24, 2002 the Campaign For Tobacco-Free Kids ("CTFK") filed an amendment to the Citizens Petition that they previously had filed on December 18, 2001 (Docket No. 01P-0572). The purpose of this amending letter was to note that the CTFK allegedly "has discovered significant, new evidence, regarding the marketing and sale of Ariva™, that warrants your consideration and immediate attention". That important evidence consisted of photographs of boxes of Ariva™ smokeless compressed tobacco cigalett™ bits on store shelves in what the CTFK represented are several CVS stores in Washington, DC and the vicinity. These photographs are described as showing Ariva™ "on the shelf separate from every other tobacco product, including every other smokeless product in the store." In reality, the copies of the photographs that accompanied CTFK's filing (copies of which are Attachment 1) show Ariva™ on the shelf directly above several shelves of cigarettes, a fact which the CTFK conveniently chose to ignore. What these photographs clearly depict is that CVS is complying with the requirement that Ariva™ be placed on shelves in the same location as other tobacco products. As a result, access is limited and valid proof of age can be determined.

In fact, as a smokeless tobacco product, Ariva™ is sold under the same rules and regulations as other tobacco products. In many states this includes restrictions on where the product must be kept, and in all states this requires that valid proof of age be presented for purchase. This is very important to Star Scientific, for one of the central

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tenets of the company's Policy Statement (a copy of which is Attachment 2) is that every effort should be made to keep all tobacco products out of the hands of children and adolescents.

The CTFK also notes that Ariva™ was placed "on the same shelf next to an FDA-approved nicotine replacement product, namely NicoDermCQ™" and that this "demonstrates that Ariva™ is being sold as a smoking cessation aid, and is further evidence of Star's intent to sell Ariva™ as a drug". Such an assertion is baseless and without any merit whatsoever. To the contrary, the photographs attached to the submission show Ariva™ being sold in the same location as other tobacco products (evidenced by columns of cigarettes). The product placement in the photo, instead, begs the question why an FDA-approved smoke cessation drug product is kept in the same location in those stores as tobacco products? NicoDerm™ is a nicotine delivery system expressly labeled to help people stop smoking; it is not a tobacco product or an alternative to tobacco products. Smoking cessation drug products would more logically be kept in the section within the pharmacy (or store) with other over-the-counter drug products. Are we to infer from this placement that it is GlaxoSmithKline's intent to sell NicoDerm™ and Nicorette™ to smokers for nicotine maintenance when they are in smoke-free environments?

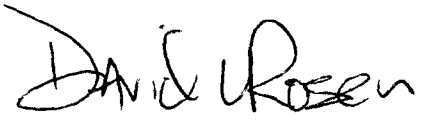
Contrary to the assertions in the CTFK's June 24 letter, no new ground is being plowed in this supplemental submission to FDA. Instead, it appears that the CTFK would use any means to push for FDA regulation of tobacco products as drugs or foods, regardless of the facts. The US Congress currently is considering several proposed bills that would create a regulatory scheme for tobacco products overseen by FDA. Star Scientific has publicly supported comprehensive, rational regulation of ALL tobacco products by FDA since 1999. The company is opposed only to selective regulation of one tobacco product and not others. CTFK's submission appears to evince the continuing belief that any means to the regulatory end is acceptable, even when it is just plain wrong.

The CTFK's comments do not contribute any new information concerning the legal question of whether the Food and Drug Administration ("FDA") has the authority to regulate Ariva™ as a "drug" or "food" under the Federal Food, Drug and Cosmetic Act ("FDCA.") Further, as our attached response demonstrates, the CTFK's comments both ignore important facts and wrongly imply that Ariva is being improperly marketed when, in reality, retailers have been legally and appropriately selling Ariva in the same manner

as other tobacco products. The CTFK's comments should therefore not be accorded any weight in considering the above referenced Citizen Petition.

We maintain the firm belief that Star Scientific's smokeless compressed tobacco product Ariva™ falls outside of FDA's jurisdiction pursuant to the Supreme Court decision in FDA v. Brown & Williamson Tobacco Corporation, 529 U.S. 120 (2000) and that the Petition is without merit and should be denied.

Respectfully submitted,



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Enclosures

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